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10/040,900	01/09/2002	William H. Harris	37697-0039	8865

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,900

Applicant(s)

HARRIS ET AL.

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 43-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 43-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Claim Objections

Claims 42, 43, 65-78, 79, 89, 90, 92, 93, and 95 are objected to because of the following informalities:

In claims 42, 65-78, 89, 90, 92, 93, and 95, the parent application PCT/US99/16070 does support the subject matter claimed herein to a three-cup prosthesis of a shell, acetabular cup, and a femur cup where the cup sizes are in the range of 35 mm to 70 mm. It appears that the Applicant is trying to claim the features of two embodiments as if they are of the same embodiment (Figure 1's embodiment combined with Figure 8's embodiment). There is no suggestion from the specification that this can be done. It also suggests that the present application is a continuation-in-part of the parent application PCT/US99/16070. For this reason, these claims lack proper antecedent basis from the specification.

The specification is also objected to as failing to provide proper antecedent basis for the claimed subject matter of claims 42, 65-78, 89, 90, 92, 93, and 95. See 37 CFR 1.75(d) (1) and MPEP § 608.01(o). Correction of the following is required:

The parent application PCT/US99/16070 does not support the subject matter claimed herein to a three-cup prosthesis of a shell, acetabular cup, and a femur cup. For this reason, these claims lack proper antecedent basis from the specification.

In claim 43, on line 5, in claim 65, lines 7-8, in claim 79, on line 7 and in claim 89, on line 7, the language "cup comprises wear-resistant cross-linked UHMWPE that resists embrittlement" is confusing in view of the fact that "cup comprises" was previously recited and it is not clear whether these are new features or replacement

Art Unit: 3738

features. The Examiner suggests changing this language to ---cross-linked UHMWPE is wear resistant and resists embrittlement--- in order to overcome this objection.

Specification Objections

In the specification, on page 13, line 25, it appears that "cups" should be ---cup's- -- in order to not be grammatically awkward.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 37-41, 43-59, 61-62, 64-89, 91, 92, 94, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townley et al (US 6,096,084) in view of McKellop et al (US 6,165,220).

Townley meets the claim language where the acetabular cup as claimed is met by the porous cobalt chromium layer and/or the cement layer (301) of Townley, and the femur cup as claimed is met by the cup (300) of Townley. The cup thickness is obviously greater than 1 mm by inspection of the drawings and comparing the thickness of the cup the diameter of the ball; see Figures 1-8 as well as column 4, line 24 to column 6, line 35 and column 7, lines 65-68. However, Townley fails to disclose a "crosslinked" UHMWPE cup material as claimed. McKellop, however, teaches that it was known to crosslink similar prosthetic cups in order to improve wear resistance; see the front page thereof as well as column 2, lines 12-18. Hence, it is the Examiner's

Art Unit: 3738

position that it would have been obvious to crosslink the internal surface of the Townley UHMWPE cup in order to improve wear resistance.

With regard to claim 41, the shell as claimed is met by the porous cobalt-chrome layer.

With regard to claims 40, 47, and 69, Townley discloses in Figure 8 a cup having a thickness about $3\text{mm}/22\text{mm}=0.14$ or 14% of the diameter of the head. Since the head can vary from 38 mm to 55 mm, the shell thickness can vary from about 5.3 mm to about 7.7 mm. Therefore, Townley fails to disclose a shell thickness of more than about 7.7 mm. However, in Examples 1 (column 11) and Example 3 (column 14), where an 8 mm thick specimens are treated, McKellop suggests that 8 mm thick shells can be used. For this reason, the use of 8 mm thick UHMWPE cups in the Townley invention would have been obvious to an ordinary artisan.

With regard to claims 50, 75, and 79, Townley discloses a ball having a diameter between 38 mm and 55 mm. Therefore, Townley fails to disclose the ball diameters claimed. However, where the difference between the prior art the claims is a relative dimensions and the claimed dimensions would not perform differently that the prior art, than the claimed device is not considered patentably distinct from the prior art; see MPEP 2144.04

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

In addition, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to increase the ball diameter because Applicants have not disclosed that the 70 mm to 90 mm diameter ball provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because it would fit larger patients and give a larger wear area therefor. Therefore, it would have been an obvious matter of design choice to modify Townley to obtain the invention as specified in the claims.

With regard to claims 54, 55, 70, 71, the Examiner asserts that these claimed parameters are inherently present in the material disclosed by Townley as modified by McKellop because it is the same crosslinked material claimed and disclosed.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Townley and McKellop as applied to claim 1 above, and further in view of DeCarlo, Jr. (US 4,524,467). Townley fails to disclose the varying degrees of movement as claimed. However, DeCarlo discloses that greater degrees of freedom with partial hemispheric portions were known to the art; see the abstract and figures. Hence, it is the Examiner's position that it would have been obvious to put partial hemispheric portions in the Townley device for the same reasons that DeCarlo does the same.

Claims 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townley and McKellop as applied to claim 1 above, and further in view of Teinturier (US 4,385,405). Townley fails to disclose an ovoid head as claimed. However, Teinturier teaches that it was known to make contact surfaces for ovoid heads; see column 4,

Art Unit: 3738

lines 18-26. Therefore, it would have been obvious to make ovoid heads in the Townley device in order to correspond to the shape of the cup of Teinturier.

With regard to claims 42, 90, and 93, these claims are considered to contain allowable subject matter but are objected to as not having clear antecedent support from the specification.

Response to Arguments

Applicant's arguments filed February 22, 2005 have been fully considered but they are not persuasive or were rendered moot.

In response to the argument that there is antecedent basis for the three-cup system, the Examiner does not agree and has added further explanation of this position in the objection.

Applicants argued that there was no motivation to combine McKellop with Townley. In response, the Examiner asserts that the motivation is provided by McKellop in the abstract for crosslinking the polyethylene, to reduce wear debris.

Applicants argue that since McKellop does not disclose use in very large heads, it does not avoid the pitfalls associated with large heads. However, the Examiner asserts that McKellop need not teach use with very large heads in order to be show obviousness therein. Since it generically teaches reduced wear for polyethylene cup bearing surfaces, it is a sufficient teaching for Townley that uses polyethylene cup bearing surfaces in the same art. In summary, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of

Art Unit: 3738

references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Response to Amendment

The declaration filed under 37 CFR 1.132 filed February 22, 2005 is insufficient to overcome the rejection of the claim based upon the applied prior art as set forth in the last Office action because:

(1) The objective evidence and inventor's arguments are not supported by actual proof. Rather, the objective evidence, in the form of prior art citations, merely suggested that some in the art had evidence that a larger head size, along with other factors, attributed to higher wear rates.

(2) Exhibit 1 (Elfeck) suggested that larger head sizes and younger more active patients resulted in higher wear rate, but no actual proof was provided. Actual proof constitutes a test of the claimed device (the entire claimed range) against the closest prior art under the same conditions. Exhibit 2 (Livermore) concluded that there was a difference in wear between 28 mm and 32 mm diameter surfaces but that the differences "were not statistically significant." Again, no actual proof was provided and the claimed range was not tested.

(3) Elfeck and Livermore are notably not within the claimed range of 35 mm to 70 mm so no clear nexus exists between the claimed invention and the evidence provided. For this reason, it is not clear that the larger heads would produce greater wear debris than the smaller ones disclosed by Elfeck and Livermore. It may be that the debris produced in the 38 mm to 55 mm head diameter range is actually smaller

Art Unit: 3738

than that of the 22 to 38 mm range due to reduced force per unit area on the cup owed to the fact that the bearing area is significantly larger.

(4) Livermore in Figure 11 shows that the 22 mm to 32 mm head diameter samples tested had wear rates all within the standard deviations of the other; see page 525. This evidence tends to show that there is no unexpected or unobvious result when the head size is increased from 22 mm to 32 mm.

(5) Exhibit 4 provided no actual data but suggested that higher wear rates were found when comparing 32 mm diameter surfaces with 28 mm and 26 mm surfaces. Again, none of the samples were within the claimed range.

(6) Exhibit 6 was primarily concerned with the effects of synovial fluids on wear. Exhibit 7 pertained to cementless fixation and not to wear. Similarly Exhibits 9 and 10 were concerned with cementless fixation and osteolysis and not to wear characteristics.

(7) To reiterate, the exhibits did not provide actual proof because they did not compare the closest prior art to the presently claimed invention in a side-by-side test. Rather, the evidence concerned devices outside of the claimed ranges.

(8) The declaration was executed by an inventor of the present application, and thus, the declarant had a vested interest in the application.

(9). Consequently, the Examiner concluded that the declaration suggested that there was a trend in the art to smaller diameter surfaces, but the Examiner concluded that this did not suggest unobviousness to one of ordinary skill to the disadvantage of using larger diameter surfaces because of prior art references such as Townley.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action unless such applications are stored in image format (i.e. IFW). Generally, those applications filed or amended after July 1, 2003 are image file wrapper (IFW) applications.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Prebilic whose telephone number is (571) 272-4758. The examiner can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738